INION
Intelligent Solution

510(k) SUMMARY
for the Inion OTPS™ 2.5/2.8/3.1 Biodegradable Screws

MANUFACTURER
Inion Ltd.
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FIN-33520 Tampere

Contact Person:
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DEVICE NAME
Trade name: Inion OTPS™ Biodegradable Mini Plating System
Common/Usual Name: Screw
Classification Name: Fixation Fastener

ESTABLISHMENT REGISTRATION NUMBER
9710629

DEVICE CLASSIFICATION AND PRODUCT CODE
Classification panel: Orthopedic
Regulatory Class: Class II
21 CFR 888.3040 – Smooth or threaded metallic bone fixation fastener, 87-HWC (Screw)

PREDICATE DEVICES
Biomet Inc.; ReUnite Bone Screw (K992301)
Linvatec Smart Screw (K003077)

DEVICE DESCRIPTION AND PRINCIPLES OF OPERATION

The Inion OTPS™ Screws are generally intended for alignment and fixation of bone fractures, osteotomies, arthrodeses and bone grafts (i.e., autografts or allografts) in the presence of appropriate additional immobilization (e.g. rigid fixation implants, cast or brace). The screws are offered in several dimensions and lengths typical for this application.

The Inion OTPS™ Screws are made of resorbable polylactic acid / trimethylenecarbonate copolymers [Poly (L-lactide-co-D,L-lactide) and poly (L-lactide-co-trimethylenecarbonate)]. The Inion OTPS™ Screw gradually loses its strength during 18-36 weeks in vivo with complete strength loss and resorption within two to four years.

EQUIVALENCE TO MARKETED PRODUCTS

Based on the performance data presented in section I of this premarket notification it is stated that the Inion OTPS™ Screws are substantially equivalent to similar marketed devices, such as Biomet ReUnite Screw 2.0/2.5 (K992301) and Linvatec SmartScrew (K003077).

The data demonstrates, that
1) Inion OTPS™ Screws retain sufficient mechanical characteristics to fulfil their intended function during bone healing according to their indications, and

2) the material and degradation by-products of the Inion OTPS™ Screws are biocompatible, with no short- or long-term safety concerns. Furthermore, there are no new risks associated with use of the Inion OTPS™ Screws as compared to the predicate biodegradable implants listed above.

Inion OTPS™ Screws are substantially equivalent to predicate Class II devices used for alignment and fixation of fractures, osteotomies, arthrodeses and bone grafts (i.e., autografts or allografts) in the presence of appropriate additional immobilization (e.g. rigid fixation implants, cast or brace), because the differences between the Inion OTPS™ Screws and these predicate devices do not raise new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 2005

Ms. Hanna Marttila
Director, Regulatory Affairs
Inion Ltd.
Lääkärinkatu 2
FIN-33520 Tampere, Finland

Re: K043142
Trade/Device Name: Inion OTPS™ 2.5/2.8/3.1 Screws
Inion OTPS™ Biodegradable Mini Plating System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: February 1, 2005
Received: February 3, 2005

Dear Ms. Marttila:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

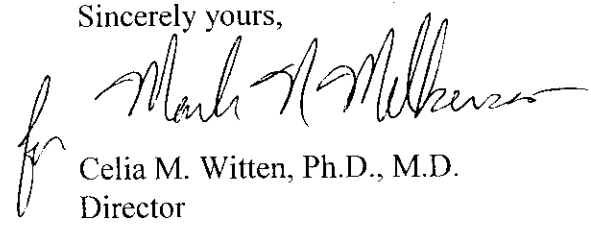
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043142

Device Name: Inion OTPS™ 2.5/2.8/3.1 Screws
Inion OTPS™ Biodegradable Mini Plating System

INDICATIONS:
These **INION OTPS™ BIODEGRADABLE FIXATION SYSTEM** implants are intended for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts (i.e., autografts or allografts) in the presence of appropriate additional immobilization (e.g., rigid fixation implants, cast or brace).

CONTRAINDICATIONS:
These **INION OTPS™ BIODEGRADABLE FIXATION SYSTEM** implants are not intended for use in and are contraindicated for:

- High-load bearing indications (e.g., diaphyseal fractures of long bones) unless used in conjunction with traditional rigid fixation.
- Spine indications.
- Active or potential infection.
- Patient conditions including limited blood supply, insufficient quantity or quality of bone; and where patient cooperation cannot be guaranteed (e.g., alcoholism, drug abuse).

Prescription Use Yes AND/OR Over-The-Counter Use No
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043142